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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,768	02/28/2002	Hans-Henrik Ipsen	478.1.012 DIV	2423

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WATOV & KIPNES, P.C.
P.O. Box 247
Princeton Junction, NJ 08550

EXAMINER

PADMANABHAN, KARTIC

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 12/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/085,768

Applicant(s)

IPSEN ET AL.

Examiner

Kartic Padmanabhan

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48,54,60,66,72 and 99-110 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48,54,60,66,72 and 99-110 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/339,545.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group VI in the reply filed on 11/4/04 is acknowledged.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 09/339,545, filed on 6/24/99. *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 48, 54, 60, 66, 72, and 99-110 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claim 48 is rejected as vague and indefinite for the recitation of "detection/measurement" in steps (g') and (id'). It is unclear if applicant is claiming **only one** of the detection and measurement of the complex or if applicant is claiming the both the detection **and** measurement of the complex. In addition, in step (f'), applicant should insert "label" before "compound to make clear to which compound the claim is referring in that step.
6. Claim 48 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: 1) the way in which the components of the three-component solid

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phase complex are bound together to form the complex in step (a'); 2) the way in which the label compound interacts with the three-component solid phase complex in step (d') to form the four-component solid phase complex; and 3) the way in which the components of the four-component solid phase complex are bound together to form the complex in step (ia'). Applicant has merely recited the components without reciting how the components cooperate with one another.

7. Claim 48 is rejected as vague and indefinite for the recitation of "determining the content of the said antibody" in step (i'). Hasn't this already been done using the protocol of step (h')? If this is different, applicant must recite in what way this is different in purpose and effect. In addition, applicant must recite from where (i.e., what type of sample, etc.) antibody content is determined.

8. Claim 48 is rejected as vague and indefinite for the recitation of comparing measurements to evaluate and/or predict the effect of treatment, as recited in step (j') because it is unclear how the measurements will be used to predict or evaluate the effect of treatment.

9. In claims 54, 60, 66, 72, and 99-108, applicant should begin the claim with "The method."

10. Claim 54 and 60 are rejected as vague and indefinite for the recitation of "if added" at the end of the claims. Component (iv) is required in the claim, so if it is not added, applicant must recite in what way it becomes available to interact with the other components.

11. Claim 72 recites the limitation "the start of and during the treatment period." There is insufficient antecedent basis for this limitation in the claim. In addition, the claim is rejected as vague and indefinite for the recitation of using a temporal change as the basis for evaluating

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and/or predicting the effect of treatment because applicant has not recited the manner in which the change may be used for this purpose.

12. Claim 99 is rejected as vague and indefinite for the recitation of "detection/measurement" and "detecting/measuring." It is unclear if applicant is claiming **only one** of the detection and measurement or if applicant is claiming the both detection **and** measurement.

13. In claim 102, applicant should correct the term "(ia' ')" because there is no such step.

14. Claims 107 and 108 recite the limitation "the start of and during the treatment period." There is insufficient antecedent basis for this limitation in the claims. In addition, the claims are rejected as vague and indefinite for the recitation of using a temporal change as the basis for evaluating and/or predicting the effect of treatment because applicant has not recited the manner in which the change may be used for this purpose.

Allowable Subject Matter

15. Claims 48, 54, 60, 66, 72, and 99-110 are allowable over the prior art of record.

16. Claims 48, 54, 60, 66, 72, and 99-110 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

17. The following is a statement of reasons for the indication of allowable subject matter:

The present application claims a method of evaluating and/or predicting effect of a Specific Allergy Vaccination treatment comprising the steps of performing a measurement of two different washed and labeled quaternary complexes and comparing these measurements, wherein the comparison is used to evaluate and/or predict effect of the Specific Allergy Vaccination treatment.

The closest prior art of relevance are due to Johansen et al. (US Pat. 6,087,188), Berger et al. (US Pat. 4,891,313), and Calenoff (WO 98/16829).

Johansen et al. teach a two site immunoassay for an antibody with a chemiluminescent label and biotin bound ligand, wherein an antibody in a sample is detected using a labeling compound and comprising the steps of 1) mixing a) a ligand antigen, antibody or hapten bound to biotin with the sample, b) an antibody directed against the antibody to be detected bound to paramagnetic particles, and c) a chemiluminescent acridinium compound bound to avidin or streptavidin to form a solid phase complex, 2) separating the solid phase from the liquid phase, and 3) analyzing the separated solid phase.

Berger et al. teach a method for the determination of a component of a sample comprising the formation and determination of quaternary complexes. The quaternary complex is formed between a solid phase bound receptor which binds to a whole, unlabelled monoclonal antibody but not to a labeled Fab fragment or a labeled monoclonal antibody, a whole monoclonal antibody which binds to the analyte the analyte itself, and a labeled Fab fragment of the monoclonal antibody.

Calenoff teaches an organism-specific and allergen-specific antibody capture assay which is suitable for the detection of immunoglobulins directed to specific organisms and for allergens, which can be used to monitor response to therapy.

The references cited above, either alone or in combination, fail to disclose or teach all the limitations of the claimed invention, as none teach the formation, detection, and comparison of two different four-component complexes to evaluate and/or predict effect of the Specific Allergy Vaccination treatment.

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Claims 48, 54, 60, 66, 72, and 99-110 are thus novel and unobvious over the cited art of record.

Conclusion

Claims 48, 54, 60, 66, 72, and 99-110 are allowable over the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 571-272-0825. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kartic Padmanabhan
Patent Examiner
Art Unit 1641

KP

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800-1641

12/10/04